

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0287613	<b>(X3) Date Survey Completed</b>  02/06/2024
<b>Name of Provider or Supplier</b>  Boca Nephrology Pa	<b>Street Address, City, State</b>  2900 N Military Trl Ste 195, Boca Raton, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Recertification survey was conducted from January 22, 2024 to February 6, 2024. Boca Nephrology PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records, and interview, the Laboratory Director and Testing Personnel failed to sign the attestation form for PT for specialty of Hematology for four (2022 1st, 2nd; 2023 2nd, 3rd) of six (2022 1st, 2nd, 3rd; 2023 1st, 2nd, 3rd) events reviewed. Findings: Review of the American Proficiency Institute (API) PT instructions noted, "Signature Required - For all PT results, an attestation must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." Review of the API PT attestation forms showed, the Testing Personnel and the Laboratory Director had not signed the attestation for the 1st and 2nd events of 2022, and the 2nd and 3rd events in 2023. On 01/22/2024 at 2:12 PM, Testing Personnel acknowledged the attestations were not signed.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:  
Based on review of Proficiency Testing (PT) records, and interview, the Laboratory Director failed to sign the Proficiency Evaluation form for PT for specialty of Hematology for six of six (2022 1st, 2nd, 3rd; 2023 1st, 2nd, 3rd) events reviewed. Findings: Review of the American Proficiency Institute (API) PT records showed, the laboratory did not have any Proficiency Evaluation forms available for review On 01/22/2024 at 2:15 PM, Testing Personnel acknowledged there were no Proficiency Evaluation signed by the Laboratory Director

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of the hematology analyzer, and interview, the laboratory failed to perform quality control lot to lot comparisons from 01/04/2024 to 04/2023 for hematology controls. Findings: Review of the Cell-Dyn 1800 Systems Operator's Manual noted, "New control material lots must be analyzed in parallel with current lots prior to their expiration." No documentation of a lot to lot comparisons of hematology controls were available for review On 01/22/2024 at 4:08 PM, the Testing Personnel stated the laboratory did not perform lot to lot comparisons of the hematology controls.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of the Patient Chart Report, and interview, the laboratory failed to include address of the laboratory and the address of the laboratory they sent specimens to for additional testing for three of three (#1 - #3) reports. Findings:

Review of the Patient Chart Reports that listed the patients laboratory results, showed the address of the laboratory and the address of the laboratory where specimens were sent to for further testing were not listed on the reports. On 01/22/2024 at 4:44 PM, Testing Personnel acknowledged the addresses of both laboratories were not listed on the reports.